510(k) SUMMARY
Emerge Medical External Fixation System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared:
Emerge Medical, Inc.
720 S Colorado Blvd., Suite 550-S
Denver, CO 80246

JUN 10 2014

Contact Person:
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Date Prepared:
March 14, 2014

Common or Usual Name:
Emerge External Fixation System
Device Classification:
Class II; 21 CFR 888.3030

Classification Name:
Single/multiple component metallic bone fixation appliances and accessories

Product Code:
KTT

Device Description:
The Emerge External Fixation System consists of combination clamp, rod-to-rod clamp, rods, pins, Schanz screws and associated instruments for site preparation and implant insertion. All components intended to be attached to bone are fabricated from medical grade stainless steel (316L Stainless Steel per ASTM F138). External clamps are fabricated from Titanium Alloy (Ti-6Al-4V-ELI per ASTM F136), and radiolucent external fixation rods are fabricated from carbon fiber. The Emerge External Fixation System is provided non-sterile.

Indications For Use:
The Emerge External Fixation is intended for use to provide treatment for long bone and pelvic fractures that require external fixation.
The system can be used for:
Stabilization of soft tissues and fractures
Polytrauma/multiple orthopedic trauma
Vertically stable pelvic fractures, or as a treatment adjunct for vertically unstable pelvic fractures
Arthrodeses and osteotomies with soft tissue problems; failures of total joints
Neutralization of fractures stabilized with limited internal fixation
Non-unions/septic non-unions
Intra-operative reductions/stabilization tool to assist with indirect reduction
Unilateral rectilinear bone segment transport or leg lengthening

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Predicate Device:
Synthes: Large External Fixation, MR Conditional (K082650)

Performance Data:
Performance testing was conducted per ASTM 1451-02 (2001). In all instances, the Emerge External Fixation System met acceptance criteria, functioned as intended and performed as well as the predicate device.

Technological Characteristics and Substantial Equivalence:
The Emerge External Fixation System is substantially equivalent to the legally marketed predicate, K082650, based on intended use, basic design, materials, sizing and performance. The systems utilize the same principles of operation allowing for unilateral, stacked, bilateral or modular frame configurations.

The systems contain similar components including large combination clamp (rod to pin clamp), rod-to-rod clamp, rods, pins, and Schanz screws; but have slight geometric differences in clamp designs. The large combination clamp and the rod-to rod clamp of the subject device use different geometrical features to lock the rotation of the clamp bodies with respect to each other when compared to the same style predicate clamps. Additionally, the subject and predicate devices have different shaped clamp body styles.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 10, 2014

Emerge Medical, Incorporated
Ms. Michelle Potvin
Vice President of Quality Assurance
720 South Colorado Boulevard
Suite 550-S
Denver, Colorado 80246

Re: K140675
Trade/Device Name: Emerge External Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTT
Dated: March 27, 2014
Received: March 28, 2014

Dear Ms. Potvin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) K140675

Device Name: **Emerge External Fixation System**

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices